The claims of the present application are directed to a method of monitoring or assessing treatment of a disease or condition with a drug that produces free radicals or a drug that reduces free radicals. The Examiner has failed to demonstrate even a *prima facie* case that this claimed invention would have been obvious at the time it was made.

Bar-Or et al. is directed to the diagnosis of one specific condition - ischemia (see, *e.g.*, column 1, lines 7-11, column 2, lines 20-45, of Bar-Or et al.). Bar-Or et al. does not teach or suggest monitoring or assessing the effectiveness of the treatment of patients with drugs that produce free radicals or reduce free radicals.

In the present Office Action, the Examiner states:

> It is the examiner's position that Bar-Or et al. teach or suggest monitoring or assessing the effectiveness of treatment of patients for example in column 2, lines 23-25 Bar-Or et al. recite "A further object of the invention is to provide a method for evaluating rehabilitated patients suffering from ischemia (myocardial infraction [sic, infarction]) to determine circulatory effectiveness", in column 9 lines 34-41 Bar Or et al. recite "The results indicate that the present method can be used to detect ischemic states. The present method is effective in distinguishing between ischemic cardiogenic chest pain and non-cardiogenic chest pain. Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein."

First, the express language of lines 23-25 of column 2 makes it clear that the rehabilitation referred to would be as a result of rehabilitative treatments for ischemia, such as angioplasty. It is submitted that this statement cannot reasonably to be interpreted to mean any other kind of treatment of patients. In particular, this statement does not teach or suggest treatment of patients with drugs that produce or reduce free radicals.

As noted above, Bar-Or et al. is directed to a method of detecting ischemia. The first two sentences of lines 34-41 of column 9 simply reiterate that the Bar-Or et al. method is effective in detecting ischemia. The remainder of the quoted language is standard "boilerplate" language used in numerous patents. In the context of the Bar-Or et al. patent, the "modifications and variations" of the invention and the practice of the invention "within the scope of the appended claims" would still be for the detection of ischemia, since Bar-Or et al. is directed only to the

diagnosis of this one specific condition (see, *e.g.*, column 2, lines 20-45, and Claims 1-13 of Bar-Or et al.). In any event, this very general language in no way teaches or suggests monitoring or assessing the effectiveness of the treatment of patients with drugs that produce or reduce free radicals.

This very general language also does not provide any motivation for those skilled in the art to combine the teachings of Bar-Or et al. with those of Crapo et al. and Young et al., contrary to the Examiner's contention in the first full paragraph on page 7 of the Office Action. Indeed, Applicants submit that there is no basis in the prior art for combining the teachings of Bar-Or et al. with those of Crapo et al. and Young et al., and that the Examiner has improperly reconstructed the invention through hindsight.

In the current Office Action, the Examiner contends that reconstruction of a claimed invention based upon hindsight reasoning is proper as long as it "does not include knowledge gleaned only from applicants' disclosure," relying on *In re McLaughlin* (see last paragraph on page 7 of the Office Action). In this case, Applicants submit that the only possible reason for choosing the Crapo et al. and Young et al. references and combining them with Bar-Or et al. is as a result of knowledge the Examiner obtained by reviewing Applicants' disclosure. As noted in the previous paragraph, the very general statements at lines 34-41 of column 9 of Bar-Or et al. are inadequate to provide motivation for those skilled in the art to combine the teachings of Bar-Or et al. with those of Crapo et al. and Young et al.

Further, the Examiner's reliance on *In re McLaughlin* appears misplaced. This case was decided many years before the Court of Appeals for the Federal Circuit (CAFC) was created. Since its creation, the CAFC has made it extremely clear that hindsight reconstruction is always improper. See, *e.g.*, *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999). In particular, the prior art must be only that which a person skilled in the art would have selected without the advantage of hindsight or knowledge of the claimed invention. *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 220 USPQ 584 (Fed. Cir. 1984).

Finally, even assuming that the Examiner's interpretation of the very general statements found at lines 34-41 of column 9 of Bar-or et al. is correct, an interpretation which Applicants

strongly contend is erroneous (see above), these very general statements would not have led a person skilled in the art to select the Crapo et al. reference, the Young et al. reference or any other specific reference(s). At best, other than within the field of detection of ischemia, these statements are an invitation to experiment to find additional uses for the Bar-Or et al. method. Applicants submit that these statements do not even rise to this level, but an invitation to experiment is, of course, not the standard of obviousness. *See, e.g., In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988).

For all of the foregoing reasons, the cited references would not have made the present invention obvious. Consequently, it is respectfully requested that the Examiner withdraw this rejection.

CONCLUSIONS

It is submitted that all of the pending claims are in condition for allowance, and a speedy allowance of them is requested.

Respectfully submitted,

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